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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,254	10/14/2003	Nathalie Jongen	1/1400	4012
28518 7590 08/07/2007 MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY RD P. O. BOX 368 RIDGEFIELD, CT 06877-0368			EXAMINER MAEWALL, SNIGDHA	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 08/07/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/685,254

Applicant(s)

JONGEN ET AL.

Examiner

Snigdha Maewall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____                                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____   | 6) <input type="checkbox"/> Other: ____                           |

## DETAILED ACTION

### *Summary*

1. Receipt of Applicant's Arguments/Remarks filed on 06/28/2007 is acknowledged.  
Claim 11 is pending in this application and claim 11 will be prosecuted on the merits.

The following rejection of record is maintained.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 11 is rejected under 35 U.S.C. 102(e) as being anticipated by WO 02/089942 A1 (herein onwards ('942)).

('942) discloses a process of making an inhalable medicament as follows: Small crystals are made by mixing a solution of a desired substance with an anti-solvent in a fluidic vortex mixer in which the residence time is less than 1 s, for example 10 ms. The liquid

within the fluidic vortex mixer (12) is subjected to high intensity ultrasound from a transducer (20, 22) in or on the wall of the mixer, or coupled to a pipe supplying liquid to the mixer. The solution very rapidly becomes supersaturated, and the ultrasound can induce a very large number of nuclei for crystal growth. Small crystals, for example less than 5 micro meters are formed that may be of a suitable size for use in inhalers (abstract and the picture as shown on front page. ('942) further discloses that crystallisation apparatus of the invention may be suitable for use in crystallising a wide variety of different compounds. Some materials for which the crystallisation procedure and apparatus would be useful, in order to provide a narrow particle size distribution and so to help control bio-availability, are: analgesics such as codeine; anti-allergens such as sodium cromoglycate; antibiotics such as penicillin, cephalosporins, streptomycins, or 15 sulphonamides; antihistamines; anti-inflammatories (page 12, lines, 6-15). A tubular apparatus is depicted on pages ¼ through ¾, fig. 1 and 8.

### **Response to Arguments**

4. Applicant's arguments filed 06/28/2007 have been fully considered but they are not persuasive.

Applicant argues " that the reference does not disclose or suggest a segmented flow or discrete volumes as recited in claim 11. Indeed, the '942 reference discloses the exact opposite of segmented flow and discrete volumes of a supersaturated fluid containing medicament, that is, a continuous flow of a liquid containing medicament. This is the type of flow that the Applicants sought to avoid. Therefore, the '942 reference fails to include each and every element of .....the claimed invention and does not

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anticipate claim 11 of the invention.

Applicants arguments that the reference does not anticipate the claim is not persuasive because the preamble of the claim as recited is directed to an inhalable medicament with an aerodynamic diameter of less than 20 micrometer, preferably less than 5 micrometer and rest of the claim is drawn to the process by which the inhalable medicament is produced. It should be noted that

**PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS [MPEP 2113 [R-1].**

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case, the reference anticipating the claim teaches production of small crystals, for example less than 5 micro meters are formed that may be of a suitable size for use in inhalers (abstract and the picture as shown on front page which reads on the claimed inhalation product. Therefore, the rejection is maintained.

**5. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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